

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Dox 1450 Alexandria, Viginia 22313-1450

## NOTICE OF ALLOWANCE AND FEE(S) DUE

23914

7590

07/10/2003

STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000

|   | EXAMINER |  |
|---|----------|--|
|   | EXAMINER |  |
| _ |          |  |
|   |          |  |

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

CLASS-SUBCLASS

1624

514-303000

DATE MAILED: 07/10/2003

| í | APPLICATION NO. | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|---------------|----------------------|---------------------|------------------|
| - | APPLICATION NO. | \ FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|   | 09/995,159      | 11/27/2001    | James R. McCarthy    | PH-7345-A           | 1709             |

TITLE OF INVENTION: CRF RECEPTOR ANTAGONISTS AND METHODS RELATING THERETO

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE | PUBLICATION FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|-----------|-----------------|------------------|------------|
| nonprovisional | NO           | \$1300    | \$300           | \$1600           | 10/10/2003 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>, THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.
- B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

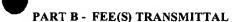
If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.
- Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Mail Stop ISSUE FEE
Commissioner for Patents
Alexandria, Virginia 22313-1450
(703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

Fax

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

23914

7590

07/10/2003

STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000 Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO. on the date indicated below.

|                    | transmitted to the USP1O, on the date indicated below. |
|--------------------|--|
| (Depositor's name) |  |
| (Signature)        |  |
| (Date)             |  |
|                    |  |

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/995,159 11/27/2001 James R. McCarthy PH-7345-A 1709

TITLE OF INVENTION: CRF RECEPTOR ANTAGONISTS AND METHODS RELATING THERETO

| APPLN. TYPE   | SMALL ENTITY   | ISSUE FEE      | PUBLICATION FEE   | TOTAL FEE(S) DUE  | DATE DUE   |
|---|--|----------------|---|---|------------|
| nonprovisional  | NO   | \$1300         | \$300   | \$1600  | 10/10/2003 |
| EXAMI<br>BALASUBRAMANIAN,                                   |  | ART UNIT       | CLASS-SUBCLASS<br>514-303000  |   |            |
| CFR 1.363).  ☐ Change of corresponde Address form PTO/SB/12 | nce address or indication of<br>ence address (or Change of<br>22) attached.<br>on (or "Fee Address" Indic<br>or more recent) attached. U | Correspondence | 2. For printing on the patent of the names of up to 3 registere or agents OR, alternatively, (single firm (having as a me attorney or agent) and the n registered patent attorneys or a is listed, no name will be printed. | d patent attorneys 2) the name of a mber a registered names of up to 2 agents. If no name |            |

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

| Please check the appropriate assignee category or categories (  | will not be printed on the patent)   | □ individual        | □ corporation or other private group entit  | ty 🛭 government |
|---|--|---------------------|---|-----------------|
| 4a. The following fee(s) are enclosed:  | 4b. Payment of Fee(s):   |                     |   |                 |
| ☐ Issue Fee   | ☐ A check in the amount  | of the fee(s) is en | closed.   |                 |
| □ Publication Fee   | Payment by credit card   | . Form PTO-2038     | B is attached.  |                 |
| □ Advance Order - # of Copies   | ☐ The Commissioner is h<br>Deposit Account Number  | ereby authorized    | by charge the required fee(s), or credit any<br>(enclose an extra copy of this form). | overpayment, to |
| Commissioner for Patents is requested to apply the Issue Fee  | and Publication Fee (if any) or to re-   | apply any previo    | usly paid issue fee to the application identi   | ified above.    |
| (Authorized Signature)  | (Date)   |                     |   |                 |
| NOTE; The Issue Fee and Publication Fee (if required) other than the applicant; a registered attorney or agent; interest as shown by the records of the United States Patent  | or the assignee or other party in  |                     |   |                 |
| This collection of information is required by 37 CFR 1.31 obtain or retain a benefit by the public which is to file (a application. Confidentiality is governed by 35 U.S.C. 122 a estimated to take 12 minutes to complete, including gather completed application form to the USPTO. Time will va case. Any comments on the amount of time you requi suggestions for reducing this burden, should be sent to the Patent and Trademark Office, U.S. Department of (22313-1450. DO NOT SEND FEES OR COMPLETED SEND TO: Commissioner for Patents, Alexandria, Virginia | re to complete this form and/or e<br>e Chief Information Officer, U.S.<br>Commerce, Alexandria, Virginia<br>FORMS TO THIS ADDRESS. |                     |   |                 |
| Under the Paperwork Reduction Act of 1995, no perso<br>collection of information unless it displays a valid OMB col   | ns are required to respond to a ntrol number.  |                     |   |                 |



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| APPLICATION NO.                          | FILING DATE                   | FIRST NAMED INVENTOR          | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------------------------|-------------------------------|-------------------------|------------------|
| 09/995,159                               | 11/27/2001                    | James R. McCarthy             | PH-7345-A               | 1709             |
| 23914                                    | 7590 07/10/2003               |                               | EXAMIN                  | ER               |
| STEPHEN B. DAVIS                         |                               | BALASUBRAMANIAN, VENKATARAMAN |                         |                  |
| PATENT DEPA                              | ERS SQUIBB COMPANY<br>ARTMENT |                               | ART UNIT                | PAPER NUMBER     |
| P O BOX 4000<br>PRINCETON, NJ 08543-4000 |                               |                               | 1624                    |                  |
|  |                               |                               | DATE MAILED: 07/10/2003 |                  |

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.



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| 09/995,159              | 11/27/2001                   | James R. McCarthy    | James R. McCarthy PH-7345-A |                  |
| 23914                   | 7590 07/10/2003              |                      | EXAMIN                      | ER               |
| STEPHEN B.              |                              |                      | BALASUBRAMANIAN,            | VENKATARAMAN     |
| BRISTOL-MY PATENT DEP   | ERS SQUIBB COMPAN<br>ARTMENT | Υ                    | ART UNIT                    | PAPER NUMBER     |
| P O BOX 4000            |                              |                      | 1624                        |                  |
| PRINCETON, UNITED STATE |                              |                      | DATE MAILED: 07/10/2003     |                  |

# Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003; Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

|  |   | <u> </u>  |  |  |  |
|--|---|---|--|--|--|
| •  | Application No.   | Applicant(s)  |  |  |  |
| Notice of Allewshility   | 09/995,159  | MCCARTHY, JAMES R.  |  |  |  |
| Notice of Allowability   | Examiner  | Art Unit  |  |  |  |
|  | Venkataraman Balasubramanian  | 1624  |  |  |  |
| The MAILING DATE of this communication apper<br>All claims being allowable, PROSECUTION ON THE MERITS IS<br>herewith (or previously mailed), a Notice of Allowance (PTOL-85)<br>NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI<br>of the Office or upon petition by the applicant. See 37 CFR 1.313  | (OR REMAINS) CLOSED in this app<br>or other appropriate communication<br>GHTS. This application is subject to   | plication. If not included will be mailed in due course. THIS   |  |  |  |
| <ol> <li>This communication is responsive to 4/30/2003.</li> <li>The allowed claim(s) is/are 4-6,19 and 20.</li> <li>The drawings filed on are accepted by the Examine</li> <li>Acknowledgment is made of a claim for foreign priority und a) All b) Some* _ c) None of the:</li> <li>Certified copies of the priority documents have</li> </ol>   | er 35 U.S.C. § 119(a)-(d) or (f).   |   |  |  |  |
| _  |   |   |  |  |  |
| <ol> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* Certified copies not received:</li> <li>Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</li> <li>The translation of the foreign language provisional application has been received.</li> </ol>  |   |   |  |  |  |
| 6. Acknowledgment is made of a claim for domestic priority ur  | nder 35 U.S.C. §§ 120 and/or 121.   |   |  |  |  |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" of below. Failure to timely comply will result in ABANDONMENT of to the submitted of the su | this application. THIS THREE-MON itted. Note the attached EXAMINER on(s) why the oath or declaration is         | NTH PERIOD IS NOT EXTENDABLE.  2'S AMENDMENT or NOTICE OF deficient.                                  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·  | الماد الم | and a second built of Francisco   |  |  |  |
| <ul> <li>(b) ☐ including changes required by the proposed drawing of</li> <li>(c) ☐ including changes required by the attached Examiner</li> </ul>   |   |   |  |  |  |
| Identifying indicia such as the application number (see 37 CFR 1. each sheet.  | 84(c)) should be written on the drawir  | ngs in the front (not the back) of  |  |  |  |
| 9. DEPOSIT OF and/or INFORMATION about the deposit attached Examiner's comment regarding REQUIREMENT FOR T   |   |   |  |  |  |
| Attachment(s)  |   |   |  |  |  |
| <ul> <li>1 Notice of References Cited (PTO-892)</li> <li>3 Notice of Draftperson's Patent Drawing Review (PTO-948)</li> <li>5 Information Disclosure Statements (PTO-1449), Paper No</li> <li>7 Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ul>   | 4☐ Interview Summa<br>6☐ Examiner's Ame   | al Patent Application (PTO-152) ary (PTO-413), Paper No ndment/Comment ement of Reasons for Allowance |  |  |  |
|  |   | m   |  |  |  |

U.S. Patent and Trademark Office PTO-37 (Rev. 04-03) Application/Control Number: 09/995,159

Art Unit: 1624

### **DETAILED ACTION**

Applicant's response, which included amendment to claims 4 and 5, filed on #30/2003, is made of record.

Claims 4--6,19 and 20 are pending.

### REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

In view of applicants' response particularly amendment to claim 4 to exclude nonelected subject matter and amendment to claim 5 to recite specific disorders/ diseases related CRF dysfunction, both 112 second and first paragraph rejection made in the previous office action have been obviated.

The compound of formula I shown in claim 4 wherein one of A, B and C is a N and the other to are CR with specific Ar, R, R<sub>1</sub>and R<sub>2</sub> groups, and the method of use for treating anxiety, depression and other CRF related disorders as embraced in the instant invention were not found to be anticipated or rendered obvious by the prior art of record. Additionally, prior art search in the relevant art area yielded no references teaching or suggesting the compound of structure of claim 4, bearing specific Ar, R, R<sub>1</sub>and R<sub>2</sub> groups or method of use embraced in the instant claims. Therefore, the examiner noted that the claims 4-6 and 19-20 would be in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Application/Control Number: 09/995,159

Art Unit: 1624

Page 3

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

על) V. Balasubramanian

7/7/2003

MUKUND J. SHAH

SUPERVISORY PATENT EXAMINER

AU 1624